Complete Summary

GUIDELINE TITLE

American Gastroenterological Association medical position statement: irritable bowel syndrome.

BIBLIOGRAPHIC SOURCE(S)

American Gastroenterological Association medical position statement: irritable bowel syndrome. Gastroenterology 2002 Dec;123(6):2105-7. [3 references] PubMed

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Irritable bowel syndrome

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Diagnosis
Management
Treatment

CLINICAL SPECIALTY

Family Practice
Gastroenterology
Internal Medicine

INTENDED USERS

Advanced Practice Nurses
Allied Health Personnel
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To assist the physician in the clinical understanding, diagnosis, and management of patients with irritable bowel syndrome (IBS)

TARGET POPULATION

Adults with symptoms consistent with irritable bowel syndrome (IBS)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnosis

1. Symptom-based diagnostic criteria (Rome II diagnostic criteria)
2. Medical history and physical examination, and the following studies: stool Hemoccult; complete blood count; sedimentation rate; chemistries; stool for ova and parasites; colonoscopy, sigmoidoscopy. Other diagnostic studies, based on symptom subtype

Treatment/Management

1. General treatment approach, including an effective therapeutic relationship between the patient and physician; patient education and reassurance; symptom diary; dietary and lifestyle modification
2. Pharmacotherapy targeted at specific symptoms, including antispasmodic (anticholinergic) medication, tricyclic or serotonin-reuptake inhibitor antidepressants, increased dietary fiber (25 g/day), loperamide, cholestyramine and 5-HT receptor active agents such as alosetron and tegaserod
3. Psychological treatment including referral to a mental health professional for treatment of associated psychiatric disorders, such as major depression; dynamic (interpersonal) psychotherapy, cognitive-behavioral treatment, hypnosis, and stress management/relaxation

MAJOR OUTCOMES CONSIDERED

- Symptomatic improvement
- Efficacy and safety of recommended treatments (e.g., medication, psychological treatment)
- Direct and indirect health care costs

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Health Care Utilization and the Health Care Burden

Although most persons with irritable bowel sydrome (IBS) do not consult physicians, the cost to society in terms of direct medical expenses and indirect costs, such as work absenteeism, is considerable: (1) they miss 3 times as many work days as those without bowel symptoms (13.4 days vs. 4.9 days) and are more likely to report that they are too sick to work (11.3 % vs. 4.2 %); (2) there are between 2.4 and 3.5 million physician visits annually for IBS in the United States, during which 2.2 million prescriptions are written; and (3) they incur health care costs of $4044 (1995 dollars), compared with $2719 for those without IBS over the previous year. In a comprehensive assessment of burden of illness for GI illnesses in the United States, IBS was second only to esophageal reflux

disease in its prevalence (15.4 million people) and was associated with $1.6 billion in direct and $19.2 billion in indirect costs. By adding 3.5 million people suffering from chronic diarrhea, the prevalence for lower functional bowel disorders nears that of gastroesophageal reflux disease. These data have important implications with regard to the need to identify treatments that can help improve health-related quality of life and associated costs to society among a very large clinical population.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The document was approved by the American Gastroenterological Association (AGA) Clinical Practice committee on August 5, 2002, and by the AGA Governing Board on September 13, 2002.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Diagnosis

Symptom-Based Criteria

A diagnosis is based on identifying positive symptoms (e.g., Rome criteria) consistent with the condition (see Table 1 below), and excluding other conditions with similar clinical presentations in a cost-effective manner.

Table 1: Rome II Diagnostic Criteria for Irritable Bowel Syndrome (IBS)

At least 12 weeks, which need not be consecutive, in the preceding 12 months of abdominal discomfort or pain that has 2 of 3 features:

1. Relieved with defecation
2. Onset associated with a change in frequency of stool
3. Onset associated with a change in form (appearance) of stool

Symptoms that cumulatively support the diagnosis of IBS:

1. Abnormal stool frequency (for research purposes, "abnormal" may be defined as greater than three bowel movements per day and less than three bowel movements per week)
2. Abnormal stool form (lumpy/hard or loose/watery stool)
3. Abnormal stool passage (straining, urgency, or feeling of incomplete evacuation)
4. Passage of mucus
5. Bloating or feeling of abdominal distension

The diagnosis of a functional bowel disorder always presumes the absence of a structural or biochemical explanation for the symptoms.

Physical Examination and Investigations

A medical history and physical examination, and certain routine studies, are recommended to assess the presence of "alarm signs" or "red flags" (fever, weight loss, blood in stools, anemia, abnormal physical findings or blood studies, family history of irritable bowel disorders or cancer) that might require more extensive evaluation.

For screening purposes, a stool Hemoccult and complete blood count are recommended. A sedimentation rate (more so in younger patients), serum chemistries and albumin, and stool for ova and parasites can be ordered based on symptom pattern, geographic area, and relevant clinical features (e.g., predominant diarrhea, areas of endemic infection). A colonoscopy is recommended for patients over age 50 years (due to higher pretest probability of colon cancer), but in younger patients, performing a colonoscopy or sigmoidoscopy is determined by clinical features suggestive of disease (e.g., diarrhea, weight loss) and may not be indicated.

Other diagnostic studies will depend on the symptom subtype. For example, for constipation-predominant symptoms, a therapeutic trial of fiber may be sufficient. However, if symptoms are persistent, confirmation of slow colonic transit with a whole gut transit test or evaluation for obstructed defecation with anorectal motility or defecating proctography may be indicated. For diarrhea-predominant symptoms, clinical judgment will determine the choice of studies. Particularly for loose/watery stools, a lactose/dextrose H_2 breath test and serologies for celiac sprue or small bowel (for giardia, small bowel malabsorption) or colonic (for microscopic colitis) biopsies may be indicated. However, controversy exists about the threshold for ordering these tests, given limited evidence as to their sensitivity, specificity, and cost utility. If negative, a therapeutic trial of loperamide can be ordered. For patients with pain as the predominant symptom, a plain abdominal radiography during an acute episode to exclude bowel obstruction and other abdominal pathology is recommended. If negative, a therapeutic trial of an antispasmodic can be ordered. Further imaging studies (e.g., small bowel series, computerized tomography scan) of the bowel and other evaluation strategies may be modified based on the duration and severity of symptoms, changes in symptom type, or severity over time and demographic or psychosocial factors.

Treatment can then be started and the patient´s condition reevaluated in 3-6 weeks. If treatment is unsuccessful, or if further evaluation seems needed, additional studies based on symptom subtype can then be undertaken.

Treatment

The treatment strategy is based on the nature and severity of the symptoms, the characteristics and degree of functional impairment, and the presence of psychosocial difficulties affecting the course of the illness. Patients with mild symptoms usually respond to education, reassurance, and simple treatments not requiring prescription medication. A smaller group of patients with moderate

symptoms have more disability and require pharmacological treatments directed at altered gut physiology or psychological treatments. The very small proportion of patients with severe and refractory symptoms are frequently seen at referral centers and have more constant pain and psychosocial disablement. They may benefit from antidepressant treatment, psychological treatments and support, and in occasional cases, referral to a multidisciplinary pain center.

Components of the Treatment Strategy

1. General treatment approach

   For all patients, the physician should establish an effective therapeutic relationship, provide patient education and reassurance, and help with dietary and lifestyle modifications when needed. Symptom monitoring using a diary may help identify possible triggers to symptom exacerbation and may guide choices for psychological and other treatments.

2. Medication directed at the predominant symptom(s)

   For abdominal pain, consider antispasmodic (anticholinergic) medication, particularly when symptoms are exacerbated by meals, or a tricyclic antidepressant (TCA), particularly if pain is frequent or severe (see below). For constipation, increased dietary fiber (25 g/day) is recommended for simple constipation, although evidence of its effectiveness in reducing pain is mixed. For diarrhea, loperamide (2-4 mg, up to four times daily) can reduce loose stools, urgency, and fecal soiling. Cholestyramine may be considered for patients with cholecystectomy or who may have idiopathic bile acid malabsorption. Newly released agents acting at the 5-HT receptor may help painful symptoms, and must be used based on whether the stool habit is primarily diarrhea (e.g., alosetron) or constipation (e.g., tegaserod). No data exist as to the role in mixed or alternating IBS, and recommendations as to their use as first or second line treatments need to be determined based on issues of efficacy, safety, and cost. Other receptor active agents for IBS are currently under active investigation.

3. Psychological treatments

   Psychological treatments are initiated when symptoms are severe enough to impair health-related quality of life. Mental health referral may also be made for treatment of associated psychiatric disorders such as major depression or a history of abuse that interferes with adjustment to illness. To enhance patient motivation, the physician needs to explain that along with the primary care physician, the mental health professional is part of the treatment team involved in the overall plan of care.

   Cognitive-behavioral treatment, dynamic (interpersonal) psychotherapy, hypnosis, and stress management/relaxation seem to be effective in reducing abdominal pain and diarrhea (but not constipation), and also reduce anxiety and other psychological symptoms. Improvement may relate to changes in GI physiology, improved coping strategies, or in the interpretation of enteroceptive signals from the gut. Greater benefit may be expected in patients who relate symptom exacerbations to stressors, have associated

symptoms of anxiety or depression, or have symptoms of a relatively short duration, and have a waxing and waning of symptoms rather than chronic pain. No one psychological treatment seems superior, and future studies need to determine the relative efficacy of these treatments for various subgroups of patients.

4. Centrally acting medications

   Antidepressants are recommended for moderate to severe symptoms of pain and may be helpful for less severe symptoms. They have neuromodulatory and analgesic properties independent of their psychotropic effect and alter GI physiology (e.g., visceral sensitivity, motility, and secretion). In general, these benefits occur sooner and in lower dosages than when prescribed for treatment of major depression. Most studies showing benefit have evaluated TCAs (e.g., amitriptyline, desipramine), rather than selective serotonin reuptake inhibitors (SSRIs) (e.g., fluoxetine, paroxetine, sertraline) in IBS, and no comparative studies have been done. However, SSRIs are in use, particularly for patients with comorbid psychiatric (e.g., anxiety-related) disorders, and they have low side effect profiles and better safety than the TCAs. Anxiolytics are generally not recommended because of weak treatment effects, a potential for physical dependence, and interaction with other drugs and alcohol.

CLINICAL ALGORITHM(S)

The technical review companion document contains the following clinical algorithms:

- Initial evaluation by the gastroenterologist for patients with irritable bowel syndrome
- Diagnostic evaluation based on symptom subtype after initial treatments are insufficient to control patient's symptoms

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation. Evidence-based data are limited and are in the process of being developed. Therefore, the guideline recommendations are culled from consensus documents and review of existing studies.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Improved clinical understanding, diagnosis, and management of patients with irritable bowel syndrome (IBS)
- Reduced health care costs associated with IBS

POTENTIAL HARMS

Pharmacotherapy

Alosetron

A significant adverse event with an unclear relationship to alosetron is acute ischemic colitis, estimated to occur in 0.1%-1% (risk factors were not identified). The drug was withdrawn from the market in November 2000 because of these side effects, but after further evaluation was reapproved by the U.S. Food and Drug Administration (FDA) in the spring of 2002 under restrictive guidelines to be developed for its use.

Tricyclic Antidepressants (TCAs)

- Low-dose: Side effects include sedation, constipation, dry mouth/eyes, weight gain, rare sexual dysfunction
- High-dose: Side effects include sedation, hypotension, and constipation (particularly for amitriptyline, doxepin, and imipramine, over desipramine or nortriptyline), dry mouth/eyes, arrhythmias, weight gain, and sexual dysfunction. There is a greater need for dosage adjustments and a greater risk for overdose. If used in higher doses, physicians should be aware of these risks and monitor their patient expectantly.

Selective Serotonin Reuptake Inhibitors (SSRIs)

Side effects include insomnia, agitation, diarrhea, night sweats, weight loss, sexual dysfunction

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

American Gastroenterological Association medical position statement: irritable bowel syndrome. Gastroenterology 2002 Dec;123(6):2105-7. [3 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 Nov 10 (revised 2002 Dec)

GUIDELINE DEVELOPER(S)

American Gastroenterological Association - Medical Specialty Society

SOURCE(S) OF FUNDING

American Gastroenterological Association

GUIDELINE COMMITTEE

American Gastroenterological Association Clinical Practice Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline. It updates a previous version: American Gastroenterological Association medical position statement: irritable bowel syndrome. Gastroenterology 1997 Jun;112(6):2118-9.

According to the guideline developer, the Clinical Practice Committee meets three times a year to review all American Gastroenterological Association guidelines. This review includes new literature searches of electronic databases followed by expert committee review of new evidence that has emerged since the original publication date.

GUIDELINE AVAILABILITY

Electronic copies: Available from the American Gastroenterological Association (AGA) Web site.

Print copies: Available from American Gastroenterological Association, 4930 Del Ray Avenue, Bethesda, MD 20814.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- Drossman DA, Camilleri M, Mayer EA, Whitehead WE. AGA technical review on irritable bowel syndrome. Gastroenterology 2002 Dec;123(6):2108-31.

Electronic copies: Available from the American Gastroenterological Association (AGA) Gastroenterology journal Web site.

Print copies: Available from American Gastroenterological Association, 4930 Del Ray Avenue, Bethesda, MD 20814.

PATIENT RESOURCES

Not stated

NGC STATUS

This summary was completed by ECRI on June 30, 1998. It was verified by the guideline developer on December 1, 1998. This summary was updated by ECRI on May 20, 2003. The updated information was verified by the guideline developer on June 24, 2003.

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